

REMARKS

Applicants wish to thank the Examiner for the time and care taken in responding to the current claims as provided in the paper mailed October 4, 2007.

In the claims, Claims 14 through 19 have been withdrawn. Claims 1 and 2 have been amended.

Turning to the action, the Examiner has rejected Claims 1 and 8 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants traverse this rejection to the extent that it is maintained. The Examiner has also rejected Claims 1, 3-9 and 11-13 under 35 U.S.C. § 102(b) as being anticipated by KATDARE, U.S. Patent No. 4,639,458. Applicants traverse this rejection to the extent that it is maintained. The Examiner has also apparently rejected Claims 1, 3-9 and 11-13 under 35 U.S.C. § 102(b) as being anticipated by ANZAGHI, et al. (WO 02/39992). Applicants traverse this rejection to the extent that it is maintained.

The Examiner has also rejected Claims 2 and 10 under 35 U.S.C. § 103 as being unpatentable and obvious over KATDARE in view of STORM, U.S. Patent No. 7,250,176. Applicants traverse this rejection to the extent that it is maintained.

Favorable reconsideration of all claims pending herein is respectfully requested.

Turning to the action, Applicant has amended Claims 1 and 8 to delete phrases such as “such as” and “about” as requested by the Examiner. Favorable consideration is respectfully requested.

Applicants have traversed the Examiner’s rejection of claims 1, 3-9, and 11-13 as anticipated by KATDARE.

Applicants note that KATDARE discloses a direct compression quinoline carboxylic acid tablet which utilizes a non-hydrated quinoline carboxylic acid.

The Examiner asserts that KATDARE discloses each and every element of the claimed invention including a direct compression quinoline carboxylic acid tablet utilizing non-hydrated quinoline carboxylic acid. The Examiner also asserts that the tablet in KATDARE comprises norfloxacin and minimal amounts of other processing aids such as disintegrates, fillers and binders as well as lubricants with no water added.

However, there is no disclosure in KATDARE regarding the use of a stabilizer and specifically a stabilizer selected from inorganic and organic acids. Additionally, there is no disclosure in KATDARE regarding the use of a stabilizer in conjunction with the recited water content, solution, disintegration, bioavailability or any other physical properties as found in the recited composition.

Accordingly, the claimed invention is not anticipated.

Applicants have also traversed the Examiner's rejection of Claims 1, 3-9, and 11-13 as anticipated by ANZAGHI, et al. (WO 02/39992).

The Examiner asserts that ANZAGHI discloses quinolonic antibacterial agents for use in oral pharmaceutical compositions which are between 40 and 80% by weight of the total adduct. The Examiner asserts that the quinolonic agent adduct can be filtered and spray dried giving a powder form and with the addition of suitable excipients used as granules or tablets. However, ANZAGHI fails to disclose the acid stabilizer in the recited concentration to promote the physical properties discovered by Application.

The Examiner points to the use of hydrochloric acid. However, the acid source referred to ANZAGHI is used as an incidental buffering agent.

Notably, the Merch Index provides that a 1 N solution of HCl (such as that used by ANZAGHI) is generally formulated by mixing 83ml of concentrated HCl (38.0% HCl) into enough water to make a liter (Merch Index, 12th Edition, No. 4821).

The volume of 0.1 N HCl required to adjust the pH of the disclosed solution is far less than now recited in Applicant's amended claim 1 (10% wt/wt).

There simply is no anticipation of the claims now pending in this application.

Favorable reconsideration is respectfully requested.

Applicants note that the Examiner has additionally rejected claims 2 and 10 under 35 U.S.C. § 103 as being unpatentable over KATDARE in view of STORM. KATDARE has been distinguished above. STORM has been additionally cited for the use of high doses of amoxicillin in tablet form to treat bacterial infections that is as an active ingredient.

Accordingly, STORM does not cure the deficiencies of KATDARE and adds nothing to the earlier rejection based upon KATDARE. The claimed invention is not anticipated or otherwise made obvious by a combination of KATDARE and STORM.

CONCLUSION

Favorable reconsideration of all claims pending herein is respectfully requested. The Examiner is invited to contact Applicant's representative (below) if questions arise.

Respectfully submitted,

VEDDER PRICE P.C.

By: 

John J. Gresens
Registration No. 33,112

Date: April 14, 2008

222 North LaSalle Street, Suite 2600
Chicago, Illinois 60601
phone: (312) 609-7599
fax: (312) 609-5005